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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,009	08/06/2002	Carolyn K. Goldman	NIH-05111	5287
45733 7590 08/26/2008 LEYDIG, VOIT & MAYER, LTD. TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6731				
			EXAMINER JIANG, DONG	
			ART UNIT 1646	PAPER NUMBER
			MAIL DATE 08/26/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Advisory Action**  
**Before the Filing of an Appeal Brief**

**Application No.**

10/089,009

**Applicant(s)**

GOLDMAN ET AL.

**Examiner**

DONG JIANG

**Art Unit**

1646

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 15 July 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1, 3, 5, 9, 11-15, 23 and 26-29.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

/Dong Jiang/  
Primary Examiner, Art Unit 1646

Continuation of 11, does NOT place the application in condition for allowance because:

Claims 1, 3, 5, 9, 11-15, 23 and 26-29 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the previous Office Actions mailed on 6/16/06, 11/1/06, 8/23/07 and 4/15/08.

Applicants argue, in the response filed on 15 July 2008, that the Office incorrectly states that Applicants have indicated that anti-Tac did co-IP the claimed ILRAPs, and it just did not co-IP enough of the claimed ILRAPs to be visualized in the SDS-PAGE; and that Applicants' actual data show that using anti-Tac to pull down IL-2R, does not pull down enough (if any) of the claimed ILRAP so as to be identifiable by SDS-PAGE, thus, Applicants have not argued that anti-Tac and ILRAPs can significantly co-IP because there is no experimental evidence of such co-IP. Applicants' argument has been fully considered, but is not persuasive because, while it is unclear what applicants' argument means by "does not pull down enough" (even if applicants' argument that anti-Tac does not pull down enough (if any) of the claimed ILRAP so as to be identifiable by SDS-PAGE does not mean that anti-Tac did co-IP the claimed ILRAPs, and it just did not co-IP enough of the claimed ILRAPs to be visualized in the SDS-PAGE), it is less relevant now because applicants admit that there is no experimental evidence of such co-IP. Thus, the issue remains, i.e., applicants have not provided any evidence demonstrating the association of the claimed ILRAPs with IL-2R.

Applicants further argue that there is no reason for assuming, as a general principle, that a monoclonal antibody (such as anti-Tac) must co-IP every protein associated with the antigen, such that every associated protein can be visualized by SDS-PAGE; and that Applicants' data consistently indicate that anti-Tac pulls down a relatively large amount of IL-2R (the 55 kDa band), whereas 5F7 antibody pulls down a relatively small amount of IL-2R (Exhibit 3, lanes 2 and 3). Applicants' argument has been fully considered, but is not persuasive because, as addressed in the previous Office Action, the 55 kDa band in Exhibit 3 appeared across the board in all lanes including lanes 6 and 8, which are pre-cleared with anti-Tac antibody, and lane 2 (not pre-cleared with anti-Tac) appeared the same as lane 8 (pre-cleared with anti-Tac), indicating (a) that the faint 55 kDa band in lanes 2, 6 and 8 might be something non-specific; and (b) that the ILRAPs may not be associated with IL-2R as claimed. Once again, applicants have not provided evidence indicating the association of the claimed ILRAPs with IL-2R.

Claims 1, 3, 5, 9, 11-15, 23 and 26-29 remain rejected under 35 U.S.C. 102(b) as being anticipated by, or, in the alternative, under 35 U.S.C. 103(a) as obvious over Colamonici et al. (J. Immunol., 1990, 145:155-160), for the reasons of record set forth in the previous Office Actions mailed on 6/3/04, 4/19/05, 10/18/05, 6/16/06, 11/1/06, 8/23/07 and 4/15/08.

In the response filed on 15 July 2008, Applicants present similar argument as previous ones and above, and argue that applicants have provided evidence showing that the claims differ from what is disclosed in Colamonici, such as that in Exhibit 1 and Exhibit 4. Applicants' argument has been fully considered, but is not persuasive for the reasons of record (see Office Action mailed on 6/16/06, pages 3-6). Applicants' interpretation of the experimental results (Exhibit 1) is not convincing because the lower band shown in lane 3 (anti-Tac Ab) is comparable to that of 5F7 protein in lane 2 in MW, i.e., the MW of the lower band in lane 3 is well within the range of that of "5F7 protein" in lane 2. Given the broad band in lane 2, there is no basis for concluding that the band in lane 3 is not the same protein.